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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,220

12/07/2004

Luppo Edens

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EXAMINER

HUTSON, RICHARD G

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

09/22/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,220	Applicant(s) EDENS ET AL.	
	Examiner Richard G. Hutson	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-34 and 36-47 is/are pending in the application.
- 4a) Of the above claim(s) 23, 24, 27, 29-33, 38, 41, 44 and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-22, 25, 26, 28, 34-37, 39, 40, 42, 43, 45 and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/7/2010, 6/25/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/7/2010 has been entered.

Applicant's cancellation of claims 35, amendment of claim 17, 25, 28, 29 and 30, in the paper of 5/7/2010, is acknowledged. Claims 17-34, 36-47 are pending and at issue.

Claims 23, 24, 27, 29-33, 38, 41, 44, 47 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper."

Applicants filing of an information disclosure statement on 5/7/2010 and 6/25/2010, are acknowledged. Those references considered have been initialed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17, 19, 21, 25, 26, 39, 42, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Shetty et al. (U.S. 4,532,213, published 7/30/1985) as evidenced Archer et al. (Biotechnology Letters, Vol 14, No. 5, pp 357-362, May 1992).

This rejection was stated in the previous office action as it applied to previous claims 17, 19, 25. In response to this action applicants have cancelled claim 35, amended claim 17, 25, 28, 29 and 30 and traverse the rejection as it applies to the newly amended claims.

As previously stated, Shetty et al. teach methods of recovery of acid fungal proteases for their use in food, brewing and photographic industries, which comprise which comprises adding the fungus, *Aspergillus niger*, comprising a proline-specific endoprotease and an auxiliary enzyme to an aqueous medium (beverage) wherein the

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addition of said auxiliary enzyme results in further prevention or reduction of haze than is achievable with the proline-specific endoprotease alone. Applicant's specification at page 3, lines 9-13 are recognized in the recitation:

"In the framework of this invention the term "beverage" includes beverages in all stages of their preparation. Thus, a beverage is not only a beverage ready for consumption but also any composition used to prepare the beverage. For example, wort as used in beer preparation is encompassed by the term "beverage" as used herein. Also, the addition of a prolyl-specific endoprotease during the preparation of a beverage to compositions that are not or not entirely liquid is intended to fall within the method according to the invention. A prolyl-specific endoprotease added to a mash at the start of beer brewing is an example of such a composition. "

While it is admitted that Shetty et al. do not add the two different enzymes separately after their isolation or purification, Shetty et al. do add the two enzymes inherently by the addition of the culture of *Aspergillus niger* to the medium.

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Applicants continue to traverse this rejection on the following basis.

Applicants submit that the cited art fails to teach or suggest a prolyl-specific endoprotease of the claims. Applicants further submit that even if the acid fungal protease in Shetty is considered as the prolyl-specific endoprotease of the claims (which it is not), then in Shetty there is no additional auxiliary proteolytic enzyme as required by the claims. Applicants submit that the auxiliary enzyme in Shetty is presumably a glucoamylase which is not a protease or proteolytic enzyme as required by the claims. Applicants further submit that, the only reference in Shetty concerning the reduction of haze in beer can be found in column 1 , first paragraph where it is

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stated that the protease (in single form) may be used in the prevention of chill haze in beer, which would not have been sufficient for one of ordinary skill to have made the claimed invention.

Applicants amendment of the claims and applicants complete argument is acknowledged and has been carefully considered, however, is not found persuasive for the reasons previously stated and for those reasons repeated herein.

With regard to applicants first point of traversal, that the acid fungal protease in Shetty is not the acid prolyl-specific endoprotease of the claims, as previously stated, while it is admitted that Shetty et al. do not add the two different enzymes separately after their isolation or purification, Shetty et al. do add the two enzymes inherently by the addition of the culture of *Aspergillus niger* to the medium. Additionally the prolyl-specific endoprotease added to the medium by Shetty et al. is that from *Aspergillus*, the same source as applicants, and thus it has the same amino acid sequence as the prolyl-specific endoprotease taught by applicants.

With regard to applicants second point that there is Shetty does not teach the additional auxillary proteolytic enzyme as required by the claims, as previously stated, while it is admitted that Shetty et al. do not add the two different enzymes separately after their isolation or purification, Shetty et al. do add the two enzymes inherently by the addition of the culture of *Aspergillus niger* to the medium as *Aspergillus niger* comprise multiple proteases. The presence of multiple proteases in *Aspergillus niger* is well known in the art and evidenced Archer et al. (Biotechnology Letters, Vol 14, No. 5,

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pp 357-362, May 1992) who teach that *A. niger* produce and comprise a number of different proteases, including at least an endoprotease and an aspartyl protease.

With regard to applicants argument that the only reference in Shetty concerning the reduction of haze in beer can be found in column 1 , first paragraph where it is stated that the protease (in single form) may be used in the prevention of chill haze in beer, it is believed that the teaching of Shetty et al. above continues to anticipate the claimed methods and applicants attention is directed to applicants claims which are drawn to a method for the prevention or reduction of haze in a beverage ready for consumption comprising. Clearly beer is a beverage ready for consumption and applicants are again reminded that the pre-amble of the claim is interpreted as an intended use of the claimed method, a use that the method taught by Shetty et al. clearly could be used

Thus claims 17, 19, 21, 25, 26, 39, 42, and 45 are anticipated by Shetty et al. as evidenced by Archer et al. (Biotechnology Letters, Vol 14, No. 5, pp 357-362, May 1992).

Claims 17-20, 25, 26, 28, 34-37, 39, 40, 42, 43, 45, 46, are rejected under 35 U.S.C. 102(e) as being anticipated by Edens et al. (US 2004/0241791 A1, published 12/2/2004).

This rejection was stated in the previous office action as it applied to previous claims 17-20, 25, 26, 28, 34-37, 39, 40, 42, 43, 45, 46. In response to this action

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applicants have cancelled claim 35, amended claim 17, 25, 28, 29 and 30 and traverse the rejection as it applies to the newly amended claims.

As previously stated, Edens et al. teach a method of enzymatically producing a protein hydrosylate intended for flavoring and nutrient enhancement of sport drinks and juice-based beverages and beer and beer mashes, comprising incubating a proline-specific endoprotease and another endoprotease with a protein substrate intended for a beverage. Edens et al. further teach said methods wherein said proline-specific carboxypeptidase comprises an amino acid sequence which has at least 95% sequence identity to the amino acid sequence of SEQ ID NO:5 and is obtainable from *Xanthomonas*.

Applicants traverse this rejection on the basis that the present application claims the benefit of priority of priority application filed 6/7/2002, whereas the cited document published as WO2002045523 on June 13, 2002.

Applicants amendment of the claims and applicants complete traversal is acknowledged and has been carefully considered, however, is not found persuasive on the basis that applicants claimed priority to the priority document EPO 02100681.2 is not granted for the amino acid sequence of SEQ ID NO:5. Thus applicants claim of priority for the subject matter of the current claims is only granted to 5/14/2003.

Thus claims 17-20, 25, 26, 28, 34-37, 39, 40, 42, 43, 45, 46 remain anticipated by Edens et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edens et al. (US 2004/0241791 A1, published 12/2/2004).as applied to claims 17-20, 25, 26, 28, 34-37, 39, 40, 42, 43, 45, 46, above, and further in view of Edens et al. U.S. Patent No. 6,372,282 B1 published 4/16/2002).

As stated above, Edens et al. (US 2004/0241791 A1) teach a method of enzymatically producing a protein hydrosylate intended for flavoring and nutrient enhancement of sport drinks and juice-based beverages and beer and beer mashes, comprising incubating a proline-specific endoprotease and another endoprotease with a protein substrate intended for a beverage. Edens et al. (US 2004/0241791 A1) further teach said methods wherein said proline-specific carboxypeptidase comprises an amino acid sequence which has at least 95% sequence identity to the amino acid sequence of SEQ ID NO:5 and is obtainable from *Xanthomonas*.

As previously stated, Edens et al. U.S. Patent No. 6,372,282 B1 published 4/16/2002) teach methods of obtaining enzymatically hydrolyzed proteinaceous material for human consumption comprising the use of an exopeptidase in combination with one or more endopeptidases such as the aspartic acid protease, Fromase®.

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One of skill in the art at the time of the invention would have been motivated to combine the methods taught by Edens et al. (US 2004/0241791 A1) with those taught by Edens et al. U.S. Patent No. 6,372,282 B1 resulting in methods of hydrolyzing proteinaceous material for human consumption, comprising the combination of multiple proteases or peptidases including the taught prolyl-specific protease and fromase® to a beverage to hydrolyze proteinaceous material. The expectation of success is high due to the teachings of both Edens et al. refs who both teach methods of hydrolysis of proteinaceous material comprising the use of multiple proteases or peptidases. Such methods would have further resulted in predictable results given the knowledge in the field of protein hydrolysis for human consumption.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17, 18, 25, 26, 28, 34, 35, 36, 37, 39, 40, 42, 43, 45, 46, are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16, 31, 43, 45-61 of copending Application No. 10/450,022. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-16, 31, 43, 45-61 of copending Application No. 10/450,022 are drawn to a method to reduce haze in a beverage comprising adding a proline-specific endoprotease comprising the amino acid sequence of SEQ ID NO: 5 to the beverage. Additionally copending Application No. 10/450,022 teaches that additional methods of the reduction of chill haze formation in beer is the addition of papain to the beer. Thus copending Application No. 10/450,022 teaches that it would be obvious to add an auxiliary enzyme such as papain as taught by 10/450,022 to the beverage in addition to a proline-specific endoprotease to reduce the haze in the beverage.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants have requested that this rejection be held in abeyance until after the determination of allowable subject matter has been made.

Claims 17-20, 25, 26, 28, 34-37, 39, 40, 42, 43, 45, 46 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-17 of copending Application No. 10/433,747. Although the conflicting

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claims are not identical, they are not patentably distinct from each other because claims 14-17 of copending Application No. 10/433,747 are drawn to a method of enzymatically producing an protein hydrolysate from a protein substrate comprising adding a proline-specific endoprotease and one or more other endoproteases to a protein substrate, thus anticipating claims 17-20, 25, 26,28, 34-37, 39, 40, 42, 43, 45, 46 to a method of reducing haze in a beverage comprising adding a praline-specific endoprotease and an auxiliary endoprotease to a beverage.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants have requested that this rejection be held in abeyance until after the determination of allowable subject matter has been made

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mondesi Robert can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rg
9/13/2010

/Richard G Hutson/
Primary Examiner, Art Unit 1652